



July 9, 2020

Mr. Michael Jones
Boston Scientific
4100 Hamline Ave N
Saint Paul, MN 55112

Dear Mr. Jones:

On June 23, 2020, TRC Environmental Corporation (TRC) performed a test to determine the Ethylene Oxide (EtO) removal efficiency of one EtO AAT control system at the Arden Hills facility. This letter summarizes the results of that test.

The test consisted of the collection of simultaneous samples of the gas stream entering and leaving the EtO control system during an evacuation cycle of the sterilization system for 1 hour. Evacuated summa cannisters were used to collect the EtO. The summa cannisters were analyzed for EtO via gas chromatography per EPA method 18 by Atmospheric Analysis and Consulting, Inc. of Ventura, California. Volumetric flow measurements were not conducted as the sampling points were too small to fit the flow probe. The results of the test are presented in the following table:

Test Location	Total EtO Concentration (ppm)	EtO Control Device Removal Efficiency (%)
Control System Inlet 1 (Chamber 1)	245,055 ppm	
Control System Inlet 2 (Chamber 2)	201,982 ppm	-
Total Inlet Concentration	447,037 ppm	
Control System Outlet 1 Post Acid Tank	8.0 ppm	99.9982%
Control System Outlet 2 Post Beds	1.9 ppm	99.9996%

If you have any questions regarding this information, please let me know. We appreciate the continuing opportunities to provide you with our services.

Sincerely,

TRC Environmental Corporation

A handwritten signature in black ink that appears to read "David Wainio".

David Wainio
Senior Project Manager



Laboratory Results

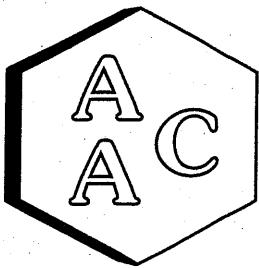
Boston Scientific AAT System 6/23/2020
Lab Results Summary
Efficiency Calculation

Sample Location	Canister Result
Chamber 1 Loading	245055 PPMV
Chamber 2 Loading	201982 PPMV
Total Inlet Loading	447037 PPMV

Sample Location	Canister Result
Outlet Loading post Acid	8.0 PPMV
Outlet Loading Post Bed	1.9 PPMV

Efficiencies

Efficiency% Post Acid	99.9982 %
Efficiency% Post Beds	99.9996 %



Atmospheric Analysis & Consulting, Inc.

CLIENT : TRC
PROJECT NAME : AAT EO System
PROJECT NUMBER : 395686
AAC PROJECT NO. : 201084
REPORT DATE : 07/07/2020

On June 24, 2020, Atmospheric Analysis & Consulting, Inc. received four (4) Six-Liter Summa Canisters for Ethylene Oxide analysis by EPA 18 Modified. Upon receipt, the samples were assigned unique Laboratory ID numbers as follows:

Client ID	Lab No.	Return Pressure (mmHg)
Chamber 1 Inlet	201084-9249	538.6
Chamber 2 Inlet	201084-9250	544.0
Outlet Post Acid	201084-9251	564.0
Outlet Post Bed	201084-9252	527.1

This analysis is performed in accordance with AAC's Quality Manual. For detailed information pertaining to specific EPA, NCASI, ASTM and SCAQMD accreditations (Methods & Analytes), please visit our website at www.aaclab.com.

I certify that this data is technically accurate, complete, and in compliance with the terms and conditions of the contract. No problems were encountered during receiving, preparation, and/or analysis of these samples. The Technical Director or his/her designee, as verified by the following signature, has authorized release of the data.

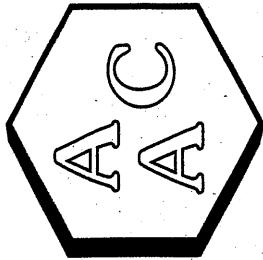
If you have any questions or require further explanation of data results, please contact the undersigned.

Sucha Parmar, Ph.D.
Technical Director

This report consists of 4 pages.



Atmospheric Analysis & Consulting, Inc.



LABORATORY ANALYSIS REPORT

CLIENT : TRC
 PROJECT NO. : 201084
 MATRIX : Air
 UNITS : ppmV

SAMPLING DATE : 06/23/2020
 RECEIVING DATE : 06/24/2020
 ANALYSIS DATE : 07/02/2020
 REPORT DATE : 07/07/2020

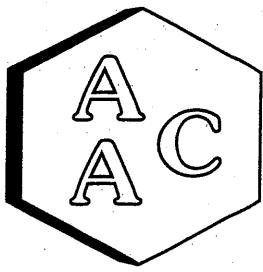
Ethylene Oxide Analysis by EPA 18 Modified

Client ID	Chamber 1 Inlet		Chamber 2 Inlet		SRL (RL x DF's)	Reporting Limit (RL)
	SRL	Result	SRL	Result		
AAC ID	201084-9249	1.7	SRL (RL x DF's)	1.7	SRL (RL x DF's)	Reporting Limit (RL)
Canister Dil. Fac.						
Analyte	Result	Analysis Dil. Fac.	Result	Analysis Dil. Fac.		
Ethylene Oxide	245055	2000	1700.0	201982	2000	1700.0
						0.5

Client ID	Outlet Post Acid		Outlet Post Bed		SRL (RL x DF's)	Reporting Limit (RL)
	SRL	Result	SRL	Result		
AAC ID	201084-9251	1.6	SRL (RL x DF's)	1.7	SRL (RL x DF's)	Reporting Limit (RL)
Canister Dil. Fac.						
Analyte	Result	Analysis Dil. Fac.	Result	Analysis Dil. Fac.		
Ethylene Oxide	8.0	1	0.8	1.9	1	0.9
						0.5

Sample Reporting Limit (SRL) is equal to Reporting Limit (RL) x Canister Dilution Factor x Analysis Dilution Factor (if applicable)

John Ferguson
 Signature
 Sugata Parmar, Ph.D.
 Technical Director



Atmospheric Analysis & Consulting, Inc.

Quality Control/Quality Assurance Report

Date Analyzed : 07/02/2020
Analyst : DL/CH
Units : ppmv

Instrument ID : FID #3
Calb Date : 07/01/20
Reporting Limit : 0.1 ppmV

I - Opening Continuing Calibration Verification - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
CCV	Spike Conc	38.00
	Result	35.08
	% Rec *	92.3

II - Method Blank - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
MB	Concentration	ND

III - Laboratory Control Spike & Duplicate - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
Lab Control Standards	Sample Conc	0.00
	Spike Conc	38.00
	LCS Result	36.34
	LCSD Result	38.08
	LCS % Rec *	95.6
	LCSD % Rec **	100.2
	% RPD **	4.7

IV - Sample & Sample Duplicate - EPA M18 Modified

AAC ID	Analyte	Ethylene Oxide
201084-9251	Sample	5.07
	Sample Dup	4.94
	Mean	5.01
	% RPD **	2.6

V - Matrix Spike & Duplicate- EPA 18 Modified

AAC ID	Analyte	Ethylene Oxide
201084-9251	Sample Conc	2.50
	Spike Conc	38.00
	MS Result	39.80
	MSD Result	41.65
	MS % Rec ***	98.2
	MSD % Rec ***	103.0
	% RPD ***	4.84

VI - Closing Continuing Calibration Verification - EPA M18 Modified

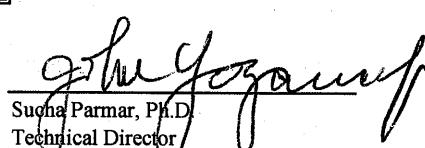
AAC ID	Analyte	Ethylene Oxide
CCV	Spike Cone	38.00
	Result	38.69
	% Rec *	101.8

* Must be 85-115%

** Must be < 25%

ND = Not Detected

<RL = less than Reporting Limit


Sonia Parmar, P.D.
Technical Director



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 Ventura, California 93003
 Phone (805) 650-1642 Fax (805) 650-1644
 E-mail: info@aaclab.com

AAC Project No. 201084

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CHAIN OF CUSTODY/ ANALYSIS REQUEST FORM

Client Name Boston Scient, Inc.		Project Name AAT EG System		Analysis Requested		Send report: Email to:	
Project Mgr (Print Name) <u>DAVID WAINO</u>		Project Number <u>395686</u>				Attn: <u>DAVID WAINO</u> <u>davidwaino@trccompanies.com</u> Phone#: <u>651-274-8771</u> Fax#:	
Sampler's Name (Print Name) <u>DAVID WAINO (TRC)</u>		Sampler's Signature <u>DJ</u>				Send invoice to:	
AAC Sample No.	Date Sampled	Sample Type	Client Sample ID/Description	Type/No. of Containers			
Can 20117	6-23-00	Air	9240 Chamber 1 Inlet	Summ 1	X		
Can 20118	6-23-00	Air	9250 Chamber 2 Inlet	Summ 1	X		
Can 20119	6-23-00	Air	9251 Outlet Post Acid	Summ 1	X		
Can 20120	6-23-00	Air	9252 Outlet Post BED	Summ 1	X		
						Turnaround Time	48-Hr
						24-Hr	Normal
						5 Day	X
						Other (Specify)	
						Special Instructions/remarks:	
Relinquished by (Signature): <u>David Waino</u>		Print Name: <u>DAVID WAINO</u>		Date/Time <u>6-23-00 1020</u>		Received by (signature): <u>Print Name</u>	
Relinquished by (Signature): <u>Gabor Pecsi</u>		Print Name: <u>Gabor Pecsi</u>		Date/Time <u>6-24-00 1024</u>		Received by (Signature): <u>Print Name</u>	
Fix Yok car + 1/2 25.3 \$3 k /c							